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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/209,541	12/11/1998	ANNA GUTOWSKA	E-1537-CIP	6863

7590 08/15/2002

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EXAMINER

MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 08/15/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

72-18

Office Action Summary

Application No.

09/209,541

Applicant(s)

GUTOWSKA, ANNA

Examiner

Jeffrey C. Mullis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 13-30 and 37-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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This Office action is in response to applicant's RCE request of 5-7-02.

All remaining rejections and/or objections follow.

The amendment filed 5-7-02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The disclosure that "as described above in order to form a gel, a sufficient number of oligo methacrylamide derivative side chains must be included in the resulting graft copolymer such that the bioactivity of the biological molecules of the backbone is not preserved and therefore the graft copolymers as described do not include polymer/protein bioconjugates.

Applicant is required to cancel the new matter in the response to this Office action.

Claims 31-36 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation that a sufficient number of side chains as in "B" of claim 31 are present such that the biodegradable polymer forms a reversible gel is new matter. It is not the position of the

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Examiner that the specification as filed does not disclose that applicant's materials form a reversible gel but rather that the side chains recited in "b" of claim 31 are not disclosed to be present in a sufficient number such that the copolymer forms a reversible gel. If the Examiner is incorrect about this, applicant is requested to point out where in the specification such a disclosure exists.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-12 and 31-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffman (USP 5,998,588).

See the Office action of Paper No. 13 of 11-28-01 at the last complete paragraph on page 3 et seq.

Claims 31-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is confusing in that Part "c" recites a characteristic rather than a component such as are described by A and B. It is suggested that "c" be eliminated since it appears to be unnecessary.

Applicant's arguments filed 5-7-02 have been fully considered but they are not deemed to be persuasive.

Applicant's amendment of Paper No. 14 with a Certificate of Mailing of 11-28-01 will be entered.

Applicant argues that the limitation that a "sufficient number of oligo methacrylamide derivative side chains to form a gel" is not new matter since it is an inherent result following the method described in the specification. While it is true that characteristics which are inherent in a method described in the specification as filed are not new matter, such characteristics are applicant's burden to prove. Absent such proof, applicants

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should point out explicit (though not necessarily *ipsis verbis*) support in the specification.

The rejection over Sasi has been withdrawn given applicant's argument that Sasi's components (AA and AG) are hydrophilic. With regard to Hoffman, it is not the position of the Examiner that Hoffman's materials never form a gel. It is the position of the Examiner that applicant's claims are not limited as to the conditions under which gel formation occurs and that Hoffman et al.'s materials reasonably appear to form a gel under conditions embraced by the instant claims although such conditions such as would induce gel formation may not be present in Hoffman. With regard to applicant's argument that his specification has been amended to make clear that a sufficient number of oligo methacrylamide derivative side chains must be included in the resulting graft copolymer such that the bioactivity of the biological molecules of the backbone is not preserved, limitations from the specification are not read into the claims. With regard to those claims not dependent from claim 31, it is noted that Example 3 of Hoffman at column 34 lines 8-17 does not form a bioconjugate.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

Serial No. 09/209,541

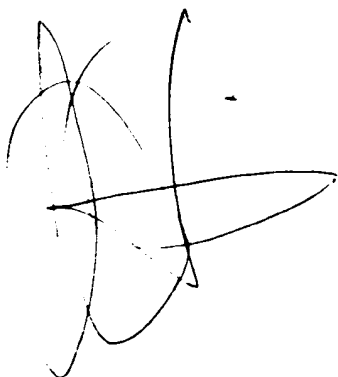
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J. Mullis:cdc

August 14, 2002

J. Mullis
Primary Examiner
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A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.